



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Confirmation Number: 8697

Cesare GALLI et al.

Attorney Docket: P66004US0

Serial No. 09/647,939

Group Art Unit: 1632

Filed: December 20, 2000

Examiner: Deborah CROUCH

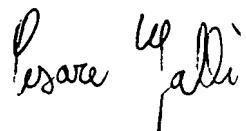
For: SOURCE OF NUCLEI FOR NUCLEAR TRANSFER

**DECLARATION UNDER 37 C.F.R. § 1.132**

1. I, Cesare Galli, am a citizen of Italy and reside at Via Persico 191-G, Cremona, I-26100, Italy.
2. I am one of the inventors of the above referenced application.
3. I am familiar with the above-referenced U.S. patent applications Serial Nos. 09/647,939 and the rejections raised by the Examiner.
4. I respectfully submit that in the method of the claims, neither optimisation of the pipette size using in transferring the donor cell, nor the use of a piezostepper, is essential for a successful cloning. The donor cell membrane will be disrupted but this can happen spontaneously. There is no requirement to take steps to force this using a particular sized pipette or a piezostepper. A piezostepper is just a tool to facilitate the job. The choice of a small pipette to assist in the rupture of the donor cell membrane is another option, but whole donor cells can be transferred with the membrane intact; it will be removed (digested) by the oocyte cytoplasm. What is important is that the donor cell (or nucleus) is introduced into the cytoplasm of the oocyte. This was done by direct injection in the method which produced Galileo, our first bull calf born in January 1999 after implanting embryos some 9 months earlier. This is the example of the patent application, which was filed before the discussion, in my later-published paper, of the ways in which the method can be possibly improved. There are several approaches to micro-injection, what is important is the actual "injection", by which I mean the introduction into the cytoplasm of the oocyte, not the way you do it. Chosing a particular pipette or using a piezostepper are steps you can take to improve the method, but you can still succeed, as we did, without them.
5. Therefore, the present application has provided sufficient disclosure that enable a person of ordinary skill in the art to practise the invention. Accordingly, withdrawal of the rejection under 35 U.S.C. 112, first paragraph, is respectfully requested.
6. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that

these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patents issuing thereon.

EXECUTED at CREMONA this 1<sup>ST</sup> day of June, 2007.

A handwritten signature in black ink that reads "Cesare Galli". The signature is fluid and cursive, with "Cesare" on the top line and "Galli" on the bottom line, with a small "u" in between.

By

[Professor Cesare Galli]